IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

PFIZER INC., WARNER-LAMBERT COMPANY LLC, PF PRISM C.V., PFIZER MANUFACTURING HOLDINGS LLC and PFIZER PFE IRELAND PHARMACEUTICALS HOLDING 1 B.V.,	)	
Plaintiff,	)	
v.	)	C.A. No. _____
DR. REDDY'S LABORATORIES, INC. and DR. REDDY'S LABORATORIES, LTD.,	)	
Defendants.	)	

COMPLAINT

Pfizer Inc., Warner-Lambert Company LLC, PF PRISM C.V., Pfizer Manufacturing Holdings LLC, and Pfizer PFE Ireland Pharmaceuticals Holding 1 B.V. (collectively "Pfizer") file this Complaint for patent infringement against Dr. Reddy's Laboratories, Inc. and Dr. Reddy's Laboratories, Ltd. (collectively, "DRL"), and by their attorneys, hereby allege as follows:

1. This is an action for patent infringement under the patent laws of the United States, Title 35, United States Code, and for a declaratory judgment of patent infringement under 28 U.S.C. §§ 2201 and 2202 and the patent laws of the United States, Title 35, United States Code, that arises out of DRL's submission of an Abbreviated New Drug Application ("ANDA") to the U.S. Food and Drug Administration ("FDA") seeking approval to commercially manufacture, use, offer for sale, sell, and/or import generic versions of IBRANCE® (Palbociclib) capsules, 75 mg, 100 mg, and 125 mg, prior to the expiration of U.S. Patent No. 6,936,612 ("the '612 patent"); U.S. Patent No. 7,208,489 ("the '489 patent"); and U.S. Patent No. 7,456,168

("the '168 patent"). These three patents are referred to collectively herein as "the patents-in-suit."

2. Dr. Reddy's Laboratories Inc. notified Pfizer by letter dated March 19, 2019 ("DRL's Notice Letter") that it had submitted to the FDA ANDA No. 213091. ("DRL's ANDA"), seeking approval from the FDA to engage in the commercial manufacture, use and/or sale of generic Palbociclib capsules, 75mg, 100 mg, and 125 mg ("DRL's ANDA Product") prior to the expiration of the patents-in-suit.

PARTIES

3. Plaintiff Pfizer Inc. is a corporation organized and existing under the laws of the State of Delaware and having a place of business at 235 East 42nd Street, New York, New York 10017. Pfizer Inc. is the holder of New Drug Application ("NDA") No. 207103 for the manufacture and sale of palbociclib tablets, 75 mg, 100 mg and 125 mg, which has been approved by the FDA.

4. Plaintiff Warner-Lambert Company LLC is a limited liability company organized and existing under the laws of the State of Delaware, and having a place of business at 235 East 42nd Street, New York, New York 10017.

5. Plaintiff PF PRISM C.V. is a limited partnership (*commanditaire vennootschap*) organized under the laws of the Netherlands, having its registered seat in Rotterdam, the Netherlands, that for all purposes is represented by and acting through its general partner Pfizer Manufacturing Holdings LLC, a limited liability company organized under the laws of the State of Delaware, and having its address at 235 East 42nd Street, New York, New York 10017.

6. Plaintiff Pfizer PFE Ireland Pharmaceuticals Holding 1 B.V. is a private limited liability company (*besloten vennootschap*) organized under the laws of the Netherlands, having

its registered seat in Rotterdam, the Netherlands, having its business address at Rivium Westlaan 142, 2909 LD, Capelle aan den IJssel, the Netherlands.

7. Upon information and belief, defendant Dr. Reddy's Laboratories, Ltd. is a company organized and existing under the laws of the Republic of India with its principal place of business at 8-2-337, Road No. 3, Banjara Hills, Hyderabad 50034, Telangana, India. Upon information and belief, Dr. Reddy's Laboratories, Ltd. is in the business of, among other things, manufacturing and selling generic versions of branded pharmaceutical drugs through various operating subsidiaries, including Dr. Reddy's Laboratories, Inc.

8. Upon information and belief, defendant Dr. Reddy's Laboratories, Inc. is a corporation organized and existing under the laws of the State of New Jersey, having a place of business at 107 College Road East, Princeton, New Jersey 08540. Upon information and belief, Dr. Reddy's Laboratories, Inc. is in the business of, among other things, manufacturing and selling generic versions of branded pharmaceutical products for the U.S. market.

9. Upon information and belief, Dr. Reddy's Laboratories, Inc. is a wholly owned subsidiary of Dr. Reddy's Laboratories, Ltd. Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. are collectively referred to herein as "DRL."

10. Upon information and belief, Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. acted in concert to prepare and submit DRL's ANDA to the FDA.

11. Upon information and belief, Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. know and intend that upon approval of DRL's ANDA, Dr. Reddy's Laboratories, Ltd. will manufacture DRL's ANDA Product and Dr. Reddy's Laboratories, Inc. will directly or indirectly market, sell, and distribute DRL's ANDA Product throughout the United States, including in Delaware. Upon information and belief, Dr. Reddy's Laboratories,

Ltd. and Dr. Reddy's Laboratories, Inc. are agents of each other and/or operate in concert as integrated parts of the same business group, including with respect to DRL's ANDA Product, and enter into agreements with each other that are nearer than arm's length. Upon information and belief, Dr. Reddy's Laboratories, Inc. participated in, assisted, and cooperated with Dr. Reddy's Laboratories, Ltd. in the acts complained of herein.

12. Upon information and belief, following any FDA approval of DRL's ANDA, Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. will act in concert to distribute and sell DRL's ANDA Product throughout the United States, including within Delaware.

JURISDICTION

13. Jurisdiction is proper in this Court pursuant to 28 U.S.C. §§ 1331, 1338(a), and 2201 and 2202.

14. Dr. Reddy's Laboratories, Ltd. is subject to personal jurisdiction in Delaware because, among other things, Dr. Reddy's Laboratories, Ltd., itself and through its wholly-owned subsidiary Dr. Reddy's Laboratories, Inc., has purposefully availed itself of the benefits and protections of Delaware's laws such that it should reasonably anticipate being haled into court here. Upon information and belief, Dr. Reddy's Laboratories, Ltd., itself and through its subsidiary Dr. Reddy's Laboratories, Inc., develops, manufactures, imports, markets, offers to sell, and/or sells generic drugs throughout the United States, including in the State of Delaware and therefore transacts business within the State of Delaware, and/or has engaged in systematic and continuous business contacts within the State of Delaware. In addition, Dr. Reddy's Laboratories, Ltd. is subject to personal jurisdiction in Delaware because, upon information and belief, it controls Dr. Reddy's Laboratories, Inc. and therefore the activities of Dr. Reddy's Laboratories, Inc. in this jurisdiction are attributed to Dr. Reddy's Laboratories, Ltd.

15. Dr. Reddy's Laboratories, Inc. is subject to personal jurisdiction in Delaware because, among other things, it has purposely availed itself of the benefits and protections of Delaware's laws such that it should reasonably anticipate being haled into court here. Upon information and belief, Dr. Reddy's Laboratories, Inc. develops, manufactures, imports, markets, offers to sell, and/or sells generic drugs throughout the United States, including in the State of Delaware and therefore transacts business within the State of Delaware related to Pfizer's claims, and/or has engaged in systematic and continuous business contacts within the State of Delaware.

16. DRL has previously used the process contemplated by the Hatch-Waxman Act to challenge branded pharmaceutical companies' patents by filing a certification of the type described in Section 505(j)(2)(A)(vii)(IV) of the FDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV), serving a notice letter on those companies, and engaging in patent litigation arising from the process contemplated by the Hatch-Waxman Act.

17. Upon information and belief, DRL, with knowledge of the Hatch-Waxman Act process, directed DRL's Notice Letter to Pfizer, an entity incorporated in Delaware, and alleged in DRL's Notice Letter that Pfizer's patents are invalid. Upon information and belief, DRL knowingly and deliberately challenged Pfizer's patent rights, and knew when it did so that it was triggering the forty-five day period for Pfizer to bring an action for patent infringement under the Hatch-Waxman Act.

18. Because Pfizer Inc. is incorporated in Delaware, Pfizer Inc. suffers injury and consequences from DRL's filing of DRL's ANDA, challenging Pfizer's patent rights, in Delaware. Upon information and belief, DRL knew that it was deliberately challenging the patent rights of a Delaware entity and seeking to invalidate intellectual property held in Delaware. DRL has been a litigant in connection with other infringement actions under the

Hatch-Waxman Act, and reasonably should have anticipated that by sending DRL's Notice Letter to Pfizer Inc., a Delaware corporation, that it would be sued in Delaware for patent infringement.

19. Upon information and belief, if DRL's ANDA is approved, DRL will directly or indirectly manufacture, market, sell, and/or distribute DRL's ANDA Product within the United States, including in Delaware, consistently with DRL's practices for the marketing and distribution of other generic pharmaceutical products. Upon information and belief, DRL regularly does business in Delaware, and its practices with other generic pharmaceutical products have involved placing those products into the stream of commerce for distribution throughout the United States, including in Delaware. Upon information and belief, DRL's generic pharmaceutical products are used and/or consumed within and throughout the United States, including in Delaware. Upon information and belief, DRL's ANDA Product will be prescribed by physicians practicing in Delaware, dispensed by pharmacies located within Delaware, and used by patients in Delaware. Each of these activities would have a substantial effect within Delaware and would constitute infringement of Pfizer's patents in the event that DRL's ANDA Product is approved before the patents expire.

20. Upon information and belief, DRL derives substantial revenue from generic pharmaceutical products that are used and/or consumed within Delaware, and which are manufactured by DRL and/or for which Dr. Reddy's Laboratories, Ltd or Dr. Reddy's Laboratories, Inc. is the named applicant on approved ANDAs. Upon information and belief, various products for which Dr. Reddy's Laboratories, Ltd or Dr. Reddy's Laboratories, Inc. is the named applicant on approved ANDAs are available at retail pharmacies in Delaware.

COUNT I - INFRINGEMENT OF THE '612 PATENT

21. Pfizer incorporates each of the preceding paragraphs 1–20 as if fully set forth herein.

22. The inventors named on the '612 patent are Mark Barvian, Richard J. Booth, John Quin, III, Joseph T. Repine, Derek J. Sheehan, Peter L. Toogood, Scott N. Vanderwel, and Hairong Zhou.

23. The '612 patent, entitled "2-(Pyridin-2-ylamino)-pyrido[2,3-d]pyrimidin-7-ones" (attached as Exhibit A), was duly and legally issued on August 30, 2005.

24. Pfizer is the owner and assignee of the '612 patent.

25. Claim 1 of the '612 patent recites "[a] compound which is 6-Acetyl-8-cyclopentyl-5-methyl-2-(5-piperazin-1-yl-pyridin-2-ylamino)-8H-pyrido[2,3-d]pyrimidin-7-one."

26. Claim 2 of the '612 patent recites "A pharmaceutical composition comprising a therapeutically effective amount of the compound according to claim 1 and a pharmaceutical carrier therefor."

27. IBRANCE® is covered by claims 1 and 2 of the '612 patent, and the '612 patent has been listed in connection with IBRANCE® in the FDA's Orange Book.

28. In DRL's Notice Letter, DRL notified Pfizer of the submission of DRL's ANDA to the FDA. The purpose of this submission was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, sale and/or importation of DRL's ANDA Product prior to the expiration of the '612 patent.

29. In DRL's Notice Letter, DRL also notified Pfizer that, as part of its ANDA, DRL had filed certifications of the type described in Section 505(j)(2)(B)(iv) of the FDCA, 21 U.S.C. § 355 (j)(2)(B)(iv), with respect to the '612 patent. On information and belief, DRL submitted

its ANDA to the FDA containing certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that the '612 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of DRL's ANDA Product.

30. DRL's ANDA Product and the use of DRL's ANDA Product are covered by claims 1 and 2 of the '612 patent.

31. In DRL's Notice Letter, DRL did not contest the infringement of claim 1 or 2 of the '612 patent on any basis other than the alleged invalidity of those claims.

32. DRL's submission of DRL's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of DRL's ANDA Product before the expiration of the '612 patent was an act of infringement of the '612 patent under 35 U.S.C. § 271(e)(2)(A).

33. On information and belief, DRL will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of DRL's ANDA Product immediately and imminently upon approval of its ANDA.

34. The manufacture, use, sale, offer for sale, or importation of DRL's ANDA Product would infringe claims 1 and 2 of the '612 patent.

35. On information and belief, the manufacture, use, sale, offer for sale, or importation of DRL's ANDA Product in accordance with, and as directed by, its proposed product labeling would infringe claims 1 and 2 of the '612 patent.

36. On information and belief, DRL plans and intends to, and will, actively induce infringement of the '612 patent when DRL's ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval. DRL's activities will be done with knowledge of the '612 patent and specific intent to infringe that patent.

37. On information and belief, DRL knows that DRL's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '612 patent, that DRL's ANDA Product is not a staple article or commodity of commerce, and that DRL's ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. On information and belief, DRL plans and intends to, and will, contribute to infringement of the '612 patent immediately and imminently upon approval of DRL's ANDA.

38. Notwithstanding DRL's knowledge of the claims of the '612 patent, DRL has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import DRL's ANDA Product with its product labeling following FDA approval of DRL's ANDA prior to the expiration of the '612 patent.

39. The foregoing actions by DRL constitute and/or will constitute infringement of the '612 patent; active inducement of infringement of the '612 patent; and contribution to the infringement by others of the '612 patent.

40. On information and belief, DRL has acted with full knowledge of the '612 patent and without a reasonable basis for believing that it would not be liable for infringement of the '612 patent; active inducement of infringement of the '612 patent; and/or contribution to the infringement by others of the '612 patent.

41. Pfizer will be substantially and irreparably damaged by infringement of the '612 patent.

42. Unless DRL is enjoined from infringing the '612 patent, actively inducing infringement of the '612 patent, and contributing to the infringement by others of the '612 patent, Pfizer will suffer irreparable injury. Pfizer has no adequate remedy at law.

COUNT II - DECLARATORY JUDGMENT
OF INFRINGEMENT OF THE '612 PATENT

43. Pfizer incorporates each of the preceding paragraphs 1–42 as if fully set forth herein.

44. The Court may declare the rights and legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case of actual controversy between Pfizer on the one hand and DRL on the other regarding DRL's infringement, active inducement of infringement, and contribution to the infringement by others of the '612 patent, and/or the validity of the '612 patent.

45. Claim 1 of the '612 patent recites "[a] compound which is 6-Acetyl-8-cyclopentyl-5-methyl-2-(5-piperazin-1-yl-pyridin-2-ylamino)-8H-pyrido[2,3-d]pyrimidin-7-one."

46. Claim 2 of the '612 patent recites "A pharmaceutical composition comprising a therapeutically effective amount of the compound according to claim 1 and a pharmaceutical carrier therefor."

47. In DRL's Notice Letter, DRL notified Pfizer of the submission of DRL's ANDA to the FDA. The purpose of this submission was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, sale and/or importation of DRL's ANDA Product prior to the expiration of the '612 patent.

48. In DRL's Notice Letter, DRL also notified Pfizer that, as part of its ANDA, DRL had filed certifications of the type described in Section 505(j)(2)(B)(iv) of the FDCA, 21 U.S.C. § 355 (j)(2)(B)(iv), with respect to the '612 patent. On information and belief, DRL submitted its ANDA to the FDA containing certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV)

asserting that the '612 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of DRL's ANDA Product.

49. DRL's ANDA Product and the use of DRL's ANDA Product are covered by claims 1 and 2 of the '612 patent.

50. In DRL's Notice Letter, DRL did not contest the infringement of claim 1 or 2 of the '612 patent on any basis other than the alleged invalidity of those claims.

51. On information and belief, DRL will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of DRL's ANDA Product immediately and imminently upon approval of its ANDA.

52. The manufacture, use, sale, offer for sale, or importation of DRL's ANDA Product would infringe claims 1 and 2 of the '612 patent.

53. On information and belief, the manufacture, use, sale, offer for sale, or importation of DRL's ANDA Product in accordance with, and as directed by, its proposed product labeling would infringe claims 1 and 2 of the '612 patent.

54. On information and belief, DRL plans and intends to, and will, actively induce infringement of the '612 patent when DRL's ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval. DRL's activities will be done with knowledge of the '612 patent and specific intent to infringe that patent.

55. On information and belief, DRL knows that DRL's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '612 patent, that DRL's ANDA Product is not a staple article or commodity of commerce, and that DRL's ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. On

information and belief, DRL plans and intends to, and will, contribute to infringement of the '612 patent immediately and imminently upon approval of DRL's ANDA.

56. Notwithstanding DRL's knowledge of the claims of the '612 patent, DRL has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import DRL's ANDA Product with its product labeling following FDA approval of DRL's ANDA prior to the expiration of the '612 patent.

57. The foregoing actions by DRL constitute and/or will constitute infringement of the '612 patent; active inducement of infringement of the '612 patent; and contribution to the infringement by others of the '612 patent.

58. On information and belief, DRL has acted with full knowledge of the '612 patent and without a reasonable basis for believing that it would not be liable for infringement of the '612 patent; active inducement of infringement of the '612 patent; and/or contribution to the infringement by others of the '612 patent.

59. Pfizer will be substantially and irreparably damaged by infringement of the '612 patent.

60. The Court should declare that the commercial manufacture, use, sale, offer for sale or importation of DRL's ANDA Product with its proposed labeling, or any other DRL drug product that is covered by or whose use is covered by the '612 patent, will infringe, induce the infringement of, and contribute to the infringement by others of the '612 patent, and that the claims of the '612 patent are not invalid.

COUNT III - INFRINGEMENT OF THE '489 PATENT

61. Pfizer incorporates each of the preceding paragraphs 1–60 as if fully set forth herein.

62. The inventors named on the '489 patent are Mark Barvian, Richard J. Booth, John Quin, III, Joseph T. Repine, Derek J. Sheehan, Peter L. Toogood, Scott N. Vanderwel, and Hairong Zhou.

63. The '489 patent, entitled "2-(pyridin-2-ylamino)-pyrido [2,3-d]pyrimidin-7-ones" (attached as Exhibit B), was duly and legally issued on April 24, 2007.

64. Pfizer is the owner and assignee of the '489 patent.

65. The '489 patent claims, *inter alia*, a compound of the formula recited in claim 1 of the '489 patent.

66. IBRANCE® is covered by one or more claims of the '489 patent, including claim 1–7 and 9 of the '489 patent, and the '489 patent has been listed in connection with IBRANCE® in the FDA's Orange Book.

67. In DRL's Notice Letter, DRL notified Pfizer of the submission of DRL's ANDA to the FDA. The purpose of this submission was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, sale and/or importation of DRL's ANDA Product prior to the expiration of the '489 patent.

68. In DRL's Notice Letter, DRL also notified Pfizer that, as part of its ANDA, DRL had filed certifications of the type described in Section 505(j)(2)(B)(iv) of the FDCA, 21 U.S.C. § 355 (j)(2)(B)(iv), with respect to the '489 patent. On information and belief, DRL submitted its ANDA to the FDA containing certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that the '489 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of DRL's ANDA Product.

69. DRL's ANDA Product and the use of DRL's ANDA Product are covered by at least claims 1–7 and 9 of the '489 patent.

70. In DRL's Notice Letter, DRL did not contest the infringement of claim 1–7 and 9 of the '489 patent on any basis other than the alleged invalidity of those claims.

71. DRL's submission of DRL's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of DRL's ANDA Product before the expiration of the '489 patent was an act of infringement of the '489 patent under 35 U.S.C. § 271(e)(2)(A).

72. On information and belief, DRL will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of DRL's ANDA Product immediately and imminently upon approval of its ANDA.

73. The manufacture, use, sale, offer for sale, or importation of DRL's ANDA Product would infringe one or more claims of the '489 patent, including, *inter alia*, claims 1–7 and 9 of the '489 patent.

74. On information and belief, the manufacture, use, sale, offer for sale, or importation of DRL's ANDA Product in accordance with, and as directed by, its proposed product labeling would infringe one or more claims of the '489 patent, including, *inter alia*, claims 1–7 and 9 of the '489 patent.

75. On information and belief, DRL plans and intends to, and will, actively induce infringement of the '489 patent when DRL's ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval. DRL's activities will be done with knowledge of the '489 patent and specific intent to infringe that patent.

76. On information and belief, DRL knows that DRL's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '489 patent, that DRL's ANDA Product is not a staple article or commodity of commerce, and that DRL's ANDA

Product and its proposed labeling are not suitable for substantial noninfringing use. On information and belief, DRL plans and intends to, and will, contribute to infringement of the '489 patent immediately and imminently upon approval of DRL's ANDA.

77. Notwithstanding DRL's knowledge of the claims of the '489 patent, DRL has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import DRL's ANDA Product with its product labeling following FDA approval of DRL's ANDA prior to the expiration of the '489 patent.

78. The foregoing actions by DRL constitute and/or will constitute infringement of the '489 patent; active inducement of infringement of the '489 patent; and contribution to the infringement by others of the '489 patent.

79. On information and belief, DRL has acted with full knowledge of the '489 patent and without a reasonable basis for believing that it would not be liable for infringement of the '489 patent; active inducement of infringement of the '489 patent; and/or contribution to the infringement by others of the '489 patent.

80. Pfizer will be substantially and irreparably damaged by infringement of the '489 patent.

81. Unless DRL is enjoined from infringing the '489 patent, actively inducing infringement of the '489 patent, and contributing to the infringement by others of the '489 patent, Pfizer will suffer irreparable injury. Pfizer has no adequate remedy at law.

COUNT IV - DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '489 PATENT

82. Pfizer incorporates each of the preceding paragraphs 1–81 as if fully set forth herein.

83. The Court may declare the rights and legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case of actual controversy between Pfizer on the one hand and DRL on the other regarding DRL's infringement, active inducement of infringement, and contribution to the infringement by others of the '489 patent, and/or validity of the '489 patent.

84. The '489 patent claims, *inter alia*, a compound of the formula recited in claim 1 of the '489 patent.

85. In DRL's Notice Letter, DRL notified Pfizer of the submission of DRL's ANDA to the FDA. The purpose of this submission was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, sale and/or importation of DRL's ANDA Product prior to the expiration of the '489 patent.

86. In DRL's Notice Letter, DRL also notified Pfizer that, as part of its ANDA, DRL had filed certifications of the type described in Section 505(j)(2)(B)(iv) of the FDCA, 21 U.S.C. § 355 (j)(2)(B)(iv), with respect to the '489 patent. On information and belief, DRL submitted its ANDA to the FDA containing certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that the '489 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of DRL's ANDA Product.

87. DRL's ANDA Product and the use of DRL's ANDA Product are covered by at least claims 1–7 and 9 of the '489 patent.

88. In DRL's Notice Letter, DRL did not contest the infringement of claim 1–7 and 9 of the '489 patent on any basis other than the alleged invalidity of those claims.

89. DRL's submission of DRL's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of DRL's

ANDA Product before the expiration of the '489 patent was an act of infringement of the '489 patent under 35 U.S.C. § 271(e)(2)(A).

90. On information and belief, DRL will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of DRL's ANDA Product immediately and imminently upon approval of its ANDA.

91. The manufacture, use, sale, offer for sale, or importation of DRL's ANDA Product would infringe one or more claims of the '489 patent, including, *inter alia*, claims 1–7 and 9 of the '489 patent.

92. On information and belief, the manufacture, use, sale, offer for sale, or importation of DRL's ANDA Product in accordance with, and as directed by, its proposed product labeling would infringe one or more claims of the '489 patent, including, *inter alia*, claims 1–7 and 9 of the '489 patent.

93. On information and belief, DRL plans and intends to, and will, actively induce infringement of the '489 patent when DRL's ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval. DRL's activities will be done with knowledge of the '489 patent and specific intent to infringe that patent.

94. On information and belief, DRL knows that DRL's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '489 patent, that DRL's ANDA Product is not a staple article or commodity of commerce, and that DRL's ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. On information and belief, DRL plans and intends to, and will, contribute to infringement of the '489 patent immediately and imminently upon approval of DRL's ANDA.

95. Notwithstanding DRL's knowledge of the claims of the '489 patent, DRL has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import DRL's ANDA Product with its product labeling following FDA approval of DRL's ANDA prior to the expiration of the '489 patent.

96. The foregoing actions by DRL constitute and/or will constitute infringement of the '489 patent; active inducement of infringement of the '489 patent; and contribution to the infringement by others of the '489 patent.

97. On information and belief, DRL has acted with full knowledge of the '489 patent and without a reasonable basis for believing that it would not be liable for infringement of the '489 patent; active inducement of infringement of the '489 patent; and/or contribution to the infringement by others of the '489 patent.

98. Pfizer will be substantially and irreparably damaged by infringement of the '489 patent.

99. The Court should declare that the commercial manufacture, use, sale, offer for sale or importation of DRL's ANDA Product with its proposed labeling, or any other DRL drug product that is covered by or whose use is covered by the '489 patent, will infringe, induce the infringement of, and contribute to the infringement by others of the '489 patent, and that the claims of the '489 patent are not invalid.

COUNT V - INFRINGEMENT OF THE '168 PATENT

100. Pfizer incorporates each of the preceding paragraphs 1–99 as if fully set forth herein.

101. The inventors named on the '168 patent are Mark Barvian, Richard J. Booth, John Quin, III, Joseph T. Repine, Derek J. Sheehan, Peter L. Toogood, Scott N. Vanderwel, and Hairong Zhou.

102. The '168 patent, entitled "2-(pyridin-2-ylamino)-pyrido [2,3-d]pyrimidin-7-ones" (attached as Exhibit C), was duly and legally issued on November 25, 2008.

103. Pfizer is the owner and assignee of the '168 patent.

104. The '168 patent claims, *inter alia*, "[a] method of treating breast cancer in a mammal comprising administering to said mammal an amount of a compound of" the formula recited in claim 1 of the '168 patent.

105. IBRANCE®, as well as methods of using IBRANCE®, are covered by one or more claims of the '168 patent, including claim 1 of the '168 patent, and the '168 patent has been listed in connection with IBRANCE® in the FDA's Orange Book.

106. In DRL's Notice Letter, DRL notified Pfizer of the submission of DRL's ANDA to the FDA. The purpose of this submission was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, sale and/or importation of DRL's ANDA Product prior to the expiration of the '168 patent.

107. In DRL's Notice Letter, DRL also notified Pfizer that, as part of its ANDA, DRL had filed certifications of the type described in Section 505(j)(2)(B)(iv) of the FDCA, 21 U.S.C. § 355 (j)(2)(B)(iv), with respect to the '168 patent. On information and belief, DRL submitted its ANDA to the FDA containing certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that the '168 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of DRL's ANDA Product.

108. The use of DRL's ANDA Product is covered by claims 1–4 of the '168 patent.

109. In DRL's Notice Letter, DRL did not contest the infringement of claim 1–4 of the '168 patent on any basis other than the alleged invalidity of those claims.

110. DRL's submission of DRL's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of DRL's ANDA Product before the expiration of the '168 patent was an act of infringement of the '168 patent under 35 U.S.C. § 271(e)(2)(A).

111. On information and belief, DRL will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of DRL's ANDA Product immediately and imminently upon approval of its ANDA.

112. The manufacture, use, sale, offer for sale, or importation of DRL's ANDA Product would directly and/or indirectly infringe claims 1–4 of the '168 patent.

113. On information and belief, the manufacture, use, sale, offer for sale, or importation of DRL's ANDA Product in accordance with, and as directed by, its proposed product labeling would directly and/or indirectly infringe claims 1–4 of the '168 patent.

114. On information and belief, DRL plans and intends to, and will, actively induce infringement of the '168 patent when DRL's ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval. DRL's activities will be done with knowledge of the '168 patent and specific intent to infringe that patent.

115. On information and belief, DRL knows that DRL's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '168 patent, that DRL's ANDA Product is not a staple article or commodity of commerce, and that DRL's ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. On information and belief, DRL plans and intends to, and will, contribute to infringement of the '168 patent immediately and imminently upon approval of DRL's ANDA.

116. Notwithstanding DRL's knowledge of the claims of the '168 patent, DRL has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import DRL's ANDA Product with its product labeling following FDA approval of DRL's ANDA prior to the expiration of the '168 patent.

117. The foregoing actions by DRL constitute and/or will constitute infringement of the '168 patent; active inducement of infringement of the '168 patent; and contribution to the infringement by others of the '168 patent.

118. On information and belief, DRL has acted with full knowledge of the '168 patent and without a reasonable basis for believing that it would not be liable for infringement of the '168 patent; active inducement of infringement of the '168 patent; and/or contribution to the infringement by others of the '168 patent.

119. Pfizer will be substantially and irreparably damaged by infringement of the '168 patent.

120. Unless DRL is enjoined from infringing the '168 patent, actively inducing infringement of the '168 patent, and contributing to the infringement by others of the '168 patent, Pfizer will suffer irreparable injury. Pfizer has no adequate remedy at law.

COUNT VI - DECLARATORY JUDGMENT
OF INFRINGEMENT OF THE '168 PATENT

121. Pfizer incorporates each of the preceding paragraphs 1–120 as if fully set forth herein.

122. The Court may declare the rights and legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case of actual controversy between Pfizer on the one hand and DRL on the other regarding DRL's infringement, active inducement of

infringement, and contribution to the infringement by others of the '168 patent, and/or validity of the '168 patent.

123. The '168 patent claims, *inter alia*, "[a] method of treating breast cancer in a mammal comprising administering to said mammal an amount of a compound of" the formula recited in claim 1 of the '168 patent.

124. In DRL's Notice Letter, DRL notified Pfizer of the submission of DRL's ANDA to the FDA. The purpose of this submission was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, sale and/or importation of DRL's ANDA Product prior to the expiration of the '168 patent.

125. In DRL's Notice Letter, DRL also notified Pfizer that, as part of its ANDA, DRL had filed certifications of the type described in Section 505(j)(2)(B)(iv) of the FDCA, 21 U.S.C. § 355 (j)(2)(B)(iv), with respect to the '168 patent. On information and belief, DRL submitted its ANDA to the FDA containing certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that the '168 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of DRL's ANDA Product.

126. The use of DRL's ANDA Product is covered by claims 1–4 of the '168 patent.

127. In DRL's Notice Letter, DRL did not contest the infringement of claim 1–4 of the '168 patent on any basis other than the alleged invalidity of those claims.

128. DRL's submission of DRL's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of DRL's ANDA Product before the expiration of the '168 patent was an act of infringement of the '168 patent under 35 U.S.C. § 271(e)(2)(A).

129. On information and belief, DRL will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of DRL's ANDA Product immediately and imminently upon approval of its ANDA.

130. The manufacture, use, sale, offer for sale, or importation of DRL's ANDA Product would directly and/or indirectly infringe claims 1–4 of the '168 patent.

131. On information and belief, the manufacture, use, sale, offer for sale, or importation of DRL's ANDA Product in accordance with, and as directed by, its proposed product labeling would directly and/or indirectly infringe claims 1–4 of the '168 patent.

132. On information and belief, DRL plans and intends to, and will, actively induce infringement of the '168 patent when DRL's ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval. DRL's activities will be done with knowledge of the '168 patent and specific intent to infringe that patent.

133. On information and belief, DRL knows that DRL's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '168 patent, that DRL's ANDA Product is not a staple article or commodity of commerce, and that DRL's ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. On information and belief, DRL plans and intends to, and will, contribute to infringement of the '168 patent immediately and imminently upon approval of DRL's ANDA.

134. Notwithstanding DRL's knowledge of the claims of the '168 patent, DRL has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import DRL's ANDA Product with its product labeling following FDA approval of DRL's ANDA prior to the expiration of the '168 patent.

135. The foregoing actions by DRL constitute and/or will constitute infringement of the '168 patent; active inducement of infringement of the '168 patent; and contribution to the infringement by others of the '168 patent.

136. On information and belief, DRL has acted with full knowledge of the '168 patent and without a reasonable basis for believing that it would not be liable for infringement of the '168 patent; active inducement of infringement of the '168 patent; and/or contribution to the infringement by others of the '168 patent.

137. Pfizer will be substantially and irreparably damaged by infringement of the '168 patent.

138. The Court should declare that the commercial manufacture, use, sale, offer for sale or importation of DRL's ANDA Product with its proposed labeling, or any other DRL drug product that is covered by or whose use is covered by the '168 patent, will infringe, induce the infringement of, and contribute to the infringement by others of the '168 patent, and that the claims of the '168 patent are not invalid.

PRAYER FOR RELIEF

WHEREFORE, Pfizer requests the following relief:

(a) A judgment that each of the patents-in-suit has been infringed under 35 U.S.C. § 271(e)(2) by DRL's submission to the FDA of DRL's ANDA;

(b) A judgment ordering that the effective date of any FDA approval of commercial manufacture, use, or sale of DRL's ANDA Products, or any other drug product that infringes or the use of which infringes one or more of the patents-in-suit, be not earlier than the latest of the expiration dates of said patents, inclusive of any extension(s) and additional period(s) of exclusivity;

(c) A preliminary and permanent injunction enjoining DRL, and all persons acting in concert with DRL, from the commercial manufacture, use, sale, offer for sale, or importation into the United States of DRL's ANDA Products, or any other drug product covered by or whose use is covered by one or more of the patents-in-suit, prior to the expiration of said patents, inclusive of any extension(s) and additional period(s) of exclusivity;

(d) A judgment declaring that the commercial manufacture, use, sale, offer for sale or importation of DRL's ANDA Products, or any other drug product which is covered by or whose use is covered by one-or-more of the patents-in-suit, prior to the expiration of said patents, will infringe, induce the infringement of, and contribute to the infringement by others of, said patents;

(e) A declaration that this is an exceptional case and an award of attorneys' fees pursuant to 35 U.S.C. § 285;

(f) Costs and expenses in this action; and

(g) Such further and other relief as this Court may deem just and proper.

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